EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF GOOD SAMARITAN HOSPITAL, PUYALLUP, PROPOSING TO ESTABLISH OPEN HEART SURGERY AND PTCA SERVICES WITHIN SPACE AT THE HOSPITAL

PROJECT DESCRIPTION

Good Samaritan Hospital (GSH) is a Washington State non-profit hospital located at 407 14th Avenue Southeast in the city of Puyallup, within Pierce County. GSH is currently a provider of Medicare and Medicaid acute care services to the residents of central and east Pierce County and surrounding areas. The hospital is licensed for 225 acute care beds, holds a three-year accreditation from the Joint Commission on Accreditation of Healthcare Organizations, and is designated as a level III trauma hospital and a level I adult trauma rehabilitation hospital. Additionally, GSH is one of four level I pediatric trauma rehabilitation hospitals in Washington State. The hospital was also recently approved to establish an intermediate care nursery and level II obstetric services. [source: CN historical files, DOH Office of Health Care Survey, and Office of Emergency Medical and Trauma Prevention]

This Certificate of Need application proposes to establish an adult open heart surgery (OHS) and PTCA program within space at the hospital. GSH will serve patients 15 years of age and older and would continue to refer patients 0-14 years to one of the established pediatric cardiac OHS hospitals in western Washington. GSH would provide the capital expenditure for the project and have all legal, operational, and management responsibilities for the OHS and PTCA program. GSH does not anticipate major construction to the hospital to accommodate the program. However, as part of a larger project, GSH is constructing a single cardiac operating room that will be dedicated exclusively to cardiac surgery, and a second existing operating room will be designated as the preferred OHS backup operating room should the need arise for a second room. The proposed PTCA services will be performed in an existing cardiac catheterization laboratory. The larger construction project is not subject to prior CN review and approval. [source: October 31, 2002, supplemental responses, p2]

The estimated capital expenditure to be incurred solely by GSH is $1,646,440, of which $1,132,423 (or 69%) is related to purchasing equipment for the new program and $254,380 (or 16%) is related to construction. The remaining costs are associated with fees and state taxes. [source: Application, p28]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the establishment of a new tertiary health service under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(f) and Washington Administrative Code (WAC) 246-310-020(1)(d)(i)(E).

APPLICATION CHRONOLOGY

The application chronology below is consistent with the Open Heart Surgery Concurrent Review Cycle outlined in WAC 246-310-132.

July 31, 2002	Letter of Intent Submitted
August 30, 2002	Application Submitted
August 31, 2002, through November 17, 2002	Department's Pre-Review Activities • 1st screening activities and responses • 2nd screening activities and responses • 3rd screening activities and responses

APPLICATION CHRONOLOGY (continued)

November 18, 2002	Department Begins Review of the Application • public comments accepted throughout review
January 16, 2003	Public Hearing Conducted
February 18, 2003	Rebuttal Documents Submitted to Department
April 14, 2003	Department's Anticipated Decision Date
May 27, 2003	Department's Actual Decision Date

AFFECTED PARTIES

As directed under WAC 246-310-110[1], the department reviewed this project under the OHS concurrent review cycle outlined in WAC 246-310-132. This application was reviewed concurrently with the joint application submitted by Evergreen Hospital Medical Center and Overlake Hospital Medical Center. Throughout the review of GSH project, five entities sought and received affected person status under WAC 246-310-010:

- Evergreen Hospital Medical Center located in the city of Kirkland within King County;
- Franciscan Health System dba St. Joseph Medical Center located in the city of Tacoma within Pierce County;
- Harrison Memorial Hospital located in the city of Bremerton within Kitsap County;
- Overlake Hospital Medical Center located in the city of Bellevue within King County; and
- University of Washington Medical Center located in the city of Seattle within King County.

SOURCE INFORMATION REVIEWED

- Good Samaritan Hospital's Certificate of Need Application dated August 29 2002 (received August 30, 2002)
- Good Samaritan Hospital's supplemental information dated October 31, 2002, December 2, 2002, and December 17, 2002 (received October 31, 2002, December 2, 2002, and December 18, 2002)
- Comments provided throughout the review of the project
- Comments received at the January 16, 2003, public hearing
- Good Samaritan Hospital's rebuttal comments dated February 18, 2004 [sic] (received February 18, 2003)
- Evergreen Hospital and Overlake Hospital's rebuttal comments dated February 14, 2003 (received February 18, 2003)
- Comprehensive Hospital Abstract Reporting System (CHARS) data obtained from the Department of Health's Office of Hospital and Patient Data Systems
- Financial feasibility and cost containment evaluation prepared by the Department of Health's Office of Hospital and Patient Data Systems (April 17, 2003)
- Historical charity care data obtained from the Department of Health's Office of Hospital and Patient Data Systems (1999, 2000, and 2001 summaries)
- Population data obtained from the Office Financial Management based on year 2000 census published January 2002.
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Emergency and trauma designation data provided by the Department of Health's Office of Emergency Medical and Trauma Prevention

[1] WAC 246-310-110 states (in summary) that the concurrent review process shall be used for all applications determined to be competing.

SOURCE INFORMATION REVIEWED (continued)

- Open Heart Surgery Standards and Need Forecasting Method under WAC 246-310-261
- Nonemergent interventional cardiology standards (PTCA) under WAC 246-310-262
- Data obtained from the Internet regarding health care worker shortages in Washington State
- Data obtained from the Internet regarding mileage and distance
- Certificate of Need Historical files

CRITERIA EVALUATION

To obtain Certificate of Need approval, GSH must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment); 246-310-261 (open heart surgery standards and methodology); and WAC 246-310-262 (nonemergent interventional cardiology standard).[2]

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of Good Samaritan Hospital proposing to establish an open heart surgery and PTCA program within space at the hospital is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

[2] Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); and WAC 246-310-240 (2) and (3).

A. Open Heart Surgery Standards and Need Forecasting Method (WAC 246-310-261)

Based on the source information reviewed, the department determines that the applicant has not met the standards and methodology criteria in WAC 246-310-261.

OHS and PTCA services are considered tertiary services as defined in WAC 246-310-010, which states (in summary) that tertiary services mean a specialized service meeting complicated medical needs of people. Tertiary services require sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care. For OHS and PTCA services, the department uses the established methodology and standards within WAC 246-310-261 to assist in its evaluation of need for the services. The following methodology calculations provided in this evaluation are for HSA #1 only. The complete methodology for Washington State is included in Appendix A attached to this evaluation.

Methodology

As a component of the need evaluation, WAC 246-310-261 outlines a seven-step methodology for forecasting OHS need within a health service area (HSA).[3] HSA's are identified in WAC 246-310-261, and are used for forecasting OHS needs. The methodology projects the number of surgeries by using the most recent three-year volumes reported for Washington State hospitals. OHS volumes are limited to Diagnosis Related Groupings (DRG) 104 through 109, inclusive. To obtain the number of OHS performed in an HSA, the department relies on historical Comprehensive Hospital Abstract Reporting System (CHARS) data provided by the Department of Health's Office of Hospital and Patient Data Systems (OHPDS).

GSH is located in HSA #1, which includes the following ten counties: Clallam, Island, Jefferson, King, Kitsap, Pierce, San Juan, Skagit, Snohomish, and Whatcom. Step #1 of the methodology is a computation of the HSA's current capacity and three-year average percentage of out-of-state use of the area hospitals. Current capacity is defined as the sum of the highest reported annual volume for each hospital within a planning area during the most recent available three years data. This evaluation relies on 1999-2001 CHARS data.[4] Data was used from the following 12 hospitals currently providing OHS and PTCA services within HSA #1.

King County	Children's Hospital & Medical Center
	Northwest Hospital
	Overlake Hospital Medical Center
	Providence Medical Center - Seattle
	Swedish Health Services
	University of Washington Medical Center
	Virginia Mason Hospital
Pierce County	Mary Bridge Children's Hospital
	St. Joseph Medical Center
	Tacoma General Hospital
Snohomish County	Providence General Medical Center
Whatcom County	PeaceHealth dba St. Joseph Hospital

On September 2001, Harrison Memorial Hospital located in Kitsap County received Certificate of Need approval to provide adult OHS and PTCA services. As of the writing of this evaluation, the

[3] HSA's are established by geographic regions appropriate for effective health planning that include a broad range of health services.
[4] Year 2002 CHARS data is not available as of the writing of this evaluation.

approved services are not yet operational, therefore, the CHARS data provided for years 1999-2001 does not include procedures performed at that facility.

GSH proposes to serve patients 15 years of age and older. Therefore, data from Children's Hospital and Medical Center and Mary Bridge Children's Hospital is included in the utilization and projections, however, their data is limited to those surgeries performed on patients 15 years of age and older.

Table I below identifies the age specific number of OHS provided within HSA #1.

Table I
Open Heart Surgery Volumes for HSA #1 Hospitals
Highest of 1999-2001 Volumes

	Age 15-44	Age 45-64	Age 65-74	Age 75+	TOTALS
Total number of discharges	314	2,094	1,506	1,294	**5,208**
Subtraction of HSA #1 three-year average number of out-of-state discharges = 3.35%	11	70	50	43	**174**
Total number of in-state discharges	303	2,024	1,456	1,251	**5,034**

As demonstrated in Table I above, the adjusted three-year high volume for HSA #1 hospitals is 5,034. To calculate steps two through seven in the methodology, the department combines like age specific volumes for years 1999-2001 for a three-year total volume for HSA #1. These totals are used to achieve three-year averages where necessary and to project OHS surgeries for year 2006.

Step #2 of the methodology requires a patient origin adjustment of the volume data to determine HSA market shares and a computation of the planning area's age specific use rates. These results are shown in Tables II and III below.

Table II
HSA #1 Use Rates Per 100,000 Based on 1999-2001 Volumes

Use Rate	Age 15-44	Age 45-64	Age 65-74	Age 75 +
3-Year Averages	15.52	214.98	655.53	589.44

Table III
HSA #1 Percentage of Market Share Based on 1999 - 2001 Volumes

	Age 15-44	Age 45-64	Age 65-74	Age 75 +
HSA #1(own market share)	99.75%	99.56%	99.50%	99.74%
HSA #2	31.73%	17.16%	16.65%	18.21%
HSA #3	26.90%	14.32%	15.23%	12.50%
HSA #4	2.03%	0.61%	0.44%	0.36%

To project the number of OHS anticipated in HSA #1 by year 2006 as directed in Step #3, the three-year average use rates (from Table II) are applied to the projected year 2006 population, which is summarized in Table IV on the following page.

Table IV
Projected Open Heart Surgeries for Year 2006 Residents of HSA #1

	Age 15-44	Age 45-64	Age 65-74	Age 75+
Projected Year 2006 Population	1,703,446	1,041,495	225,764	210,755
Average Use Rate (from Table II)	15.52	214.98	655.53	589.44
Projected # of Surgeries per 100,000 Population	264	2,239	1,480	1,242

Step #4 in the need methodology is the use of market share to project the number of Washington State residents expected to have OHS in a hospital within HSA #1 in year 2006. This calculation is derived by multiplying the projected number of surgeries shown in each corresponding HSA's Table IV within the methodology by the market share percentages shown in Table III. Table V below is a summary of this calculation.

Table V
HSA #1 Projected Number of Surgeries for Year 2006

	Age 15-44	Age 45-64	Age 65-74	Age 75 +	TOTAL
HSA #1 (own market share)	264	2,229	1,473	1,239	5,205
HSA #2	11	60	50	41	162
HSA #3	13	50	43	30	136
HSA #4	2	2	1	1	6
TOTALS	**290**	**2,342**	**1,566**	**1,311**	**5,509**

Note that whole numbers may not add due to rounding

As shown in Table V above, for year 2006, the projected number of patients to be served by the 13 hospitals within HSA #1 that either have an established OHS program, or--in the case of Harrison Memorial Hospital, will have an established OHS program--is 5,509.

Step #5 adjusts this number to include projected out-of-state activity. The 1999-2001 methodology shows a three-year average of 3.35% of HSA #1 surgeries were out-of-state residents (Table I). Applying this number for year 2006 surgery projections yields 191 out-of-state residents being projected to use OHS services in HSA #1. This results in a projected total number of surgeries in year 2006 for HSA #1, including out-of-state residents, to be 5,700.[5]

Step #6 in the methodology requires subtracting the current capacity (highest reported OHS annual volume) from the projected need. Using annual volume figures for years 1999-2001, current capacity from Table I is 5,208. Therefore, the number of additional surgeries projected in HSA #1, or the projected net need, for year 2006 is 492.[6]

Step #7 states (in summary) that if the projected net need is less than the current minimum volume of 250 procedures as required by WAC 246-310-261(3)(a), then no new programs shall be assumed to be needed in the planning area. Given that the projected net need is 492, step #7 does not apply.

The mathematical calculation portion of the methodology found in WAC 246-310-261 demonstrates that the addition of at least one OHS program is HSA #1 is reasonable. The result of the mathematical calculation is not the sole measure of determining need for an OHS program. The department must now determine whether the GSH project meets the seven standards outlined in the methodology.

[5] 5,509 plus 191.
[6] 5,700 minus 5,208.

Standards

Standard #a:

A minimum of 250 open heart surgery procedures per year shall be performed at institutions with an open heart surgery program.

GSH estimates that 168 OHS would be performed in year one, 223 in year two, and 264 by the end of the third year of operation, which is 2006. [source: application, p8] These estimates are based on written, verifiable documentation that GSH physicians have referred 284 OHS cases to other Pierce and King County hospitals in the twelve months from August 1, 2001, to July 31, 2002. [source: application, Appendix 5] As shown in step #6 of the methodology, the department projects approximately 492 additional OHS will be performed in HSA #1 by year 2006. Therefore, solely based on GSH's historical referrals, the total number of surgeries projected to be performed by the end of year three may be at least 250. This standard is met.

Standard #b:

Hospitals applying for a Certificate of Need shall demonstrate that they can meet one hundred ten percent of the minimum volume standard. To do so, the applicant hospital must provide written documentation, which is verifiable, of open heart surgeries performed on patients referred by active medical staff of the hospital. The volume of surgeries counted must be appropriate for the proposed program (i.e., pediatric and recognized complicated cases would be excluded).

The department recognizes that generally the patient's attending cardiologist is the primary influence that determines where the patient will receive OHS services and that hospitals contract with selected cardiology groups. Even though an applying hospital can demonstrate a history of referring 250 or more surgeries to institutions with OHS capabilities, it is unlikely that an applying hospital would re-capture 100% (all 250) of those referrals. Therefore, to assure that the applying facility would perform the minimum of 250 OHS by year three of operation, the standard requires institutions applying for new heart surgery programs to demonstrate it has referred a minimum of 275 or 110% of the 250 minimum number of surgeries.

As stated in standard #a above, GSH provided referral documentation for a total of 284 patients for the twelve months from August 1, 2001, to July 31, 2002. [source: Application, Appendix 5] The population of HSA #1 for residents 15 years and older is expected to reach approximately 3,181,460 by year 2006. [source: OFM projected population data] This is a 7.5% increase over the estimated year 2000 population for HSA #1. On the basis of the calculations of the projected percentage of population increase for HSA #1, the department expects this proposal would meet this standard by the end of the third year of operation. This is consistent with WAC 246-310-261(3)(g) which allows hospitals three years from the date the program is initiated to meet this standard. Further, the department previously concluded that all 284 patients would be considered consistent with standard #a. This standard has been met.

Standard #c:

No new program shall be established which will reduce an existing program below the minimum volume standard.

According to CHARS data, the following numbers of OHS were performed in HSA #1 hospitals in 2001. [source: Year 2001 CHARS data, less out of state activity]

Table VI
Year 2001 Number of Open Heart Surgeries
Performed in HSA #1 Hospitals

Facility Name/County Location	# of Surgeries
Children's Hospital & Medical Center, King County (15+ yrs)	14
Mary Bridge Children's Hospital, Pierce County (15+ yrs)	5
Northwest Hospital, King County	151
Overlake Hospital Medical Center, King County	366
PeaceHealth dba St. Joseph Hospital, Whatcom County	285
Providence General Medical Center, Snohomish County	595
Providence Medical Center - Seattle, King County	381
St. Joseph Medical Center, Pierce County	679
Swedish Health Services, King County	751
Tacoma General Hospital, Pierce County	389
University of Washington Medical Center, King County	398
Virginia Mason Hospital, King County	629

Harrison Memorial Hospital is not included in Table VI above because it received approval for adult OHS in September 2001 and, as of the writing of this evaluation, the program is not yet operational. As shown in Table VI, both Children's Hospital and Medical Center and Mary Bridge Children's Hospital are considerably below the minimum volume standard of 250 OHS. The department notes, however, that these two providers primarily serve patients under the age of 15. Therefore, the department expects both of these hospitals to have a relatively small number of OHS procedures for patients in the 15 years and older age group.

Verifiable documentation provided by GSH shows that the 284 patients were referred to four of the twelve HSA #1 area hospitals for OHS. Table VII below identifies the hospital where GSH physicians referred its 284 patients. [source: Application, Appendix 5]

Table VII
2001 Good Samaritan Hospital Open Heart Surgery Referrals

Facility Name/County Location	# of Referrals	% of 284 Total
Tacoma General Hospital, Pierce County	182	64.1%
St. Joseph Medical Center, Pierce County	99	34.8%
University of Washington Medical Center, King County	2	0.7%
Swedish Health Services, King County	1	0.4%
Total	**284**	**100.0%**

As shown in Table VII above, 281 (or 99%) of the total number of GSH patients were referred to the two Tacoma hospitals with OHS capabilities--Tacoma General Hospital (182) and St. Joseph Medical Center (99). If GSH were to re-capture 100%, or all 281, of these patients, the impact to these two hospitals is estimated to be:

- Tacoma General Hospital would serve 207 patients (389 minus 182); and
- St. Joseph Medical Center would serve 580 patients (679 minus 99).

Using the simple mathematical calculation above, approval of GSH's project would reduce Tacoma General Hospital below the 250 standard.

To demonstrate the potential impact of its proposed program, GSH provided the following information and presented the table below. [source: Application, p19, and February 18, 2004 [sic] rebuttal documents, pp12-13.]

"…the need criteria set forth in WAC 246-310-210 and -261 do not prescribe the mechanism by which the applicant is to determine the potential impact of its proposed program on existing open heart surgery providers in the service area. …Faced with no standard that outlines how to project the impact of a proposed open heart surgery program on other programs, but armed with an understanding of what typically governs open heart surgery referral patterns, GSH chose to utilize an approach in its application based on market share percentages."

DOCUMENTATION OF POTENTIAL IMPACT ON SJMC & TGH [source: GSH application, p19 and GSH rebuttal documentation, pp12-13]			
		SJMC	**TGH**
1.	Total volume 2001 adult cardiac surgery (OHS) regardless of patient residence (source: 2001 CHARS)	687	393
2.	Total volume 2001 adult OHS performed on Pierce County residents (source : 2001 CHARS)	466	333
3.	Total volume 2001 adult OHS performed on Pierce County residents-all hospitals (source: 2001 CHARS)	895	895
4.	% of Pierce County volume performed by SJMC or TGH	52.1%	37.2%
5.	Impact on SJMC and TGH of GSH's 264 cases (52.1% of 264; 37.2% of 264)	138	98
6.	SJMC and TGH volume (with GSH program) (687-138; 393-98)	549	295
7.	Less projected impact of Harrison program (from HMH CN application)	84	26
8.	**SJMC and TGH volume (with potential GSH and HMH program impacts)**	**465**	**269**

The approach used by GSH above suggests that the number of GSH patients that should be deducted from St. Joseph Hospital and Tacoma General Hospital's total number of patients is derived by:

a) dividing the number of adult OHS cases performed at each facility on all Pierce County residents (row 2 above) by the total number of OHS cases performed by all hospitals on Pierce County residents (row 3);
b) the resulting percentage of a) above (row 4) is then multiplied by 264, which is the number of OHS patients GSH projects to serve in its third year of operation;
c) the resulting number from b) above is then subtracted from each facility's total 2001 adult OHS cases (row 1). The result of this calculation, shown in row 6, is the projected impact of GSH's proposed program on the two existing OHS providers in Pierce County.

To further demonstrate that neither GSH's projected OHS program nor Harrison Memorial Hospital's (HMH) recently approved OHS program would impact St. Joseph or Tacoma General Hospitals, GSH also subtracted the potential impact of HMH's project (row 7) from c) above.

After reviewing the approach used by GSH above, the department concludes that it is flawed for the following reasons:

- The total number of OHS cases performed on Pierce County residents by all hospitals in Washington State (row 3) includes patients referred to other facilities in the state. Factors used to determine whether a patient should be referred to a facility outside Pierce County are numerous. For example, a patient may be referred because of the patient's acuity, age, or complicating diagnoses, or in some cases, the patient may be traveling outside of their resident zip code when the need for open heart surgery occurs.
- The total number of OHS cases performed on Pierce County residents by all hospitals in Washington State (row 3) is not relevant to GSH's referral patterns for OHS. This number

shows that some Pierce County residents have received their OHS in other hospitals throughout the state. Approval of this project would not change this.

- The result of using the total number of OHS cases performed on Pierce County residents by all hospitals in Washington State reverses the actual referral patterns of GSH. As shown in Table VII on page 11, in year 2001, GSH referred 182 patients to Tacoma General and 99 to St. Joseph Hospital. Using GSH's calculations above, GSH decreases its referrals to Tacoma General to 98 patients and increases referrals to St. Joseph Hospital to 138 patients. GSH did not provide any rationale in the application to suggest that a reverse in referral patterns is a reasonable assumption.

In summary, the department concludes that GSH's method used to evaluate the impact of its proposed program on existing providers is not sound. Further, GSH does not provide compelling documentation that its method is either valid or preferable to the department's direct mathematical calculation to determine impact on existing providers.

To further evaluate the impact of this GSH project on the two OHS providers in Pierce County, the department reviewed the CHARS data for year 2001 referrals to determine the acuity of the OHS patients of each hospital. The CHARS database has two acuity listings for each record. One is the facility DRG weight used to generate a case mix, and the second is a refined DRG weight. The refined weight breaks down the DRG weight into four parts. For example, DRG 105 breaks down into 1050, 1051, 1052, and 1053. Under this system, the lower number represents a lower acuity, and the higher number represents a higher acuity. Therefore, a patient with a refined DRG weight of 1053 has a higher acuity than the patient with 1051. The higher the acuity, the sicker the patient. The department's review of DRG weights revealed that of the two Pierce County OHS hospitals, generally St. Joseph Hospital serves the higher acuity patients. This conclusion is confirmed by a comparison of each hospital's average length of stay related to the refined DRG weight. It is also confirmed by the lower number of OHS patients typically referred from GSH to St. Joseph Hospital, and the higher number referred to Tacoma General Hospital.

Given that St. Joseph Hospital typically serves the higher acuity OHS patient, the department concludes that GSH would probably recapture a small number of its 99 patient referrals from that hospital. However, GSH may recapture the majority of its 182 referrals from Tacoma General because of the lower acuity of those patients. In any event, as previously stated, if GSH were to recapture 100% of its referrals from Tacoma General Hospital, the hospital would fall below the 250 minimum standard 207. Even if GSH were to recapture only 75% of its referrals from Tacoma General (137 patients), the Tacoma General would be right at the 250 minimum standard patients (252 patients).

GSH states that *"in assessing the potential for GSH's proposed open heart surgery program to reduce TGH's program below the minimum volume standard of 250 surgeries, it is critical that the CN Program recognize that during 2001, TGH experienced its lowest program volume in recent years. However, based on the first half 2002 CHARS data, the TGH program now appears to be on the rise. The following summarized 'fall and rise' of TGH open heart surgery program should nevertheless be considered by the CN program when analyzing whether GSH's program will comply with standard #c".* [source: GSH February 18, 2004 (sic) rebuttal documents, p14]

The department concurs with GSH that historical volumes must also be considered when evaluating impact on existing, established OHS programs. To assist in this evaluation, the department reviewed the historical number of OHS for St. Joseph Hospital, Tacoma General Hospital, HSA #1 as a whole, and Washington State for years 1997 through 2001. A summary of that review is shown in Table VIII on the following page.

Table VIII
Volumes for Years 1997-2001

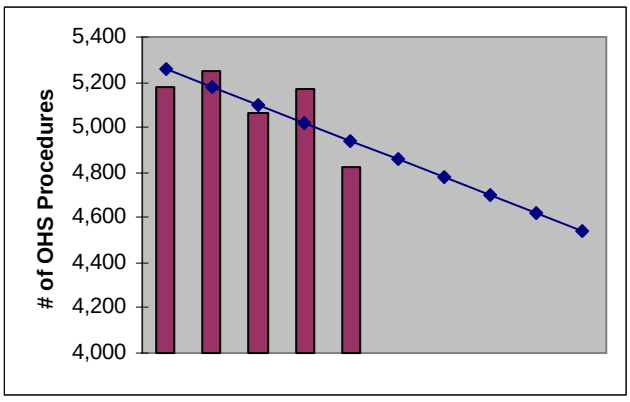
YEAR	ST. JOSEPH HOSPITAL	TACOMA GENERAL HOSPITAL	HSA #1	STATE TOTAL
1997	648	494	5,176	7,366
1998	648	516	5,251	7,277
1999	620	522	5,061	7,199
2000	681	418	5,171	7,362
2001	687	394	4,820	7,174

As shown in Table VIII, for St. Joseph Hospital, even though the number of OHS decreased from year 1998 to 1999, in general, the total number of OHS has increased from years 1997 to 2001. In contrast, Tacoma General Hospital, HSA #1, and Washington State as a whole, numbers of OHS have decreased overall from years 1997 to 2001.

Also, the department reviewed the OHS market share percentage captured by each hospital in relation to HSA #1 and the state. In 1997, St. Joseph Hospital's market share is 12.5% of HSA #1 and 8.8% of the state's volume. Year 2001 market share percentages increased to 14.2% and 9.6% respectively for St. Joseph. In 1997, Tacoma General's market share is 9.5% of HSA #1 and 6.7% of the state volume; while year 2001 market shares decreased to 8.2% and 5.4% respectively. In conclusion, OHS volumes have decreased overall from year 1997-2001 for HSA #1, Washington State as a whole, and Tacoma General Hospital. St. Joseph Hospital's volumes are increasing, however, not substantially.

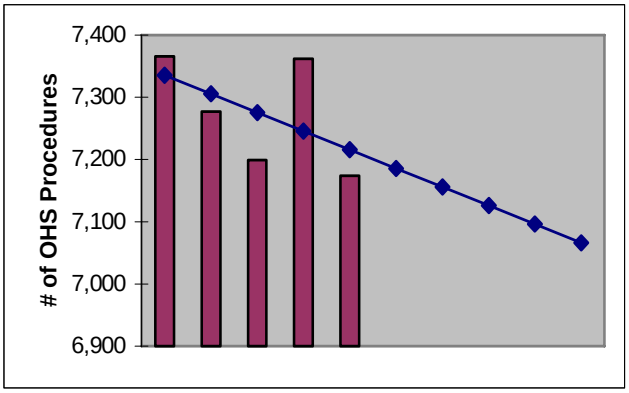
GSH also suggests that its potential impact on Tacoma General Hospital may be even less than projected using 1997-2001 CHARS data because *"based on the first half 2002 CHARS data, the TGH program now appears to be on the rise."* Using the first six months of 2002 data, GSH speculates that Tacoma General Hospital's total cardiac surgery volume will reach slightly over 400. The department does not use annualized data in its methodology projections for several reasons. Annualized data is unreliable because it does not take into account seasonal fluctuations, it is unaudited by OHPDS, and, finally, WAC 246-310-261 refers to *"three years data"* and *"annual volume"* within the methodology. As a result, GSH's assertion that Tacoma General Hospital's OHS volumes are increasing based on six months data cannot be substantiated.

Using the five years historical data for OHS, the department applied a regression analysis to determine the projected number of OHS to be performed for HSA #1 and the state. The results of the projections are shown below.



HSA #1 Trends 2002-2006

As the chart on the left illustrates, the number of OHS projected for HSA #1 is expected to substantially decrease.



Washington State Trends 2002-2006

As with the HSA #1, the chart on the left also illustrates that the number of OHS projected for Washington State is expected to substantially decrease.

The trends illustrated in the charts above demonstrate a projected decline of OHS in the state and HSA #1 based on five years OHS historical data. Data reviewed by the department suggests that the demand for cardiac services will continue to grow across the nation as the population ages, however, the demand for cardiac services is expected to shift from OHS to other interventional procedures. Many factors have led to this decline, including the increase in technological interventions and cardiac medications. Regardless of the cause, the expected and projected effect is decreased OHS volumes--in HSA #1, Washington State, and nationally.

Based on the above factors, the department concludes that approval of this project would negatively affect Tacoma General Hospital by decreasing its volume of OHS procedures below the standard of 250 OHS per year. Further, given that OHS volumes are on the decrease for the HSA and the state as a whole, approval of this project would simply not be prudent at this time. Therefore, this standard is not met.

Standard #d:
Open heart surgery programs shall have at least two board-certified cardiac surgeons, one of whom shall be available for emergency surgery twenty-four hours a day. The practice of these surgeons shall be concentrated in a single institution and arranged so that each surgeon performs a minimum of 125 open heart surgery procedures per year at that institution.

The intent of this standard is to ensure that the cardiac patient is treated by cardiac physicians and support staff that have attained the high success rate only achieved by the physician and staff volume/quality relationship with the cardiac surgeries. To meet this standard, GSH provided a copy of the draft agreement between the hospital and Starr-Wood Cardiac Management, Inc. (Starr-Wood). The draft agreement outlines the roles and responsibilities of each entity and identifies all costs associated with the agreement. Under this agreement, Starr-Wood will be responsible for start up and ongoing operations of the program, initial training of the staff, and providing the medical director. Additionally, under the agreement at least one of the Starr-Wood surgeons will be a resident in the hospital's primary service area. The agreement further states that GSH will have final authority for management and operations, recruit staff, and provide equipment and supplies for the proposed program. [source: GSH December 17, 2002, supplemental information] This standard is met provided that GSH provide a copy of the executed agreement before providing OHS or PTCA services.

Standard #e:
Institutions with open heart surgery programs shall have plans for facilitating emergency access to open heart surgery services at all times for the population they serve. These plans should, at minimum, include arrangements for addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.), and the maintenance of, or affiliation with, emergency transportation services (including contingency plans for poor weather and known traffic congestion problems).

In response to this standard, GSH is constructing a single cardiac operating room that will be dedicated exclusively to cardiac surgery, and a second existing operating room will be designated as the preferred OHS backup operating room should the need arise for a second room. If both rooms were in use and an emergent OHS patient was admitted, OHS could be performed in any of the remaining ORs as an emergent solution. In any event, GSH will require an average of 30 minutes to prepare the OR and staff for OHS.

The proposed PTCA services will be performed in an existing cardiac catheterization laboratory. GSH does not anticipate major construction to the hospital to accommodate the OHS or PTCA services. [sources: Application, p20 and October 31, 2002, supplemental responses, p2]

GSH states its cardiac surgery program will operate 24/7 and anticipates no difficulty addressing the emergency needs of the OHS population in HSA #1. For complex patients, GSH will continue to use its existing protocol for transporting to the hospitals and physicians in Tacoma. As stated in the project description portion of this analysis, GSH will serve patients 15 years of age and older. Patients 14 years and younger will primarily be referred to Mary Bridge Children's Hospital in Tacoma or Children's Hospital and Regional Medical Center in Seattle. GSH anticipates no change in these referral patterns with the establishment of the proposed OHS and PTCA services. [source: October 31, 2002, supplemental responses, p3] This standard is met.

Standard #f:
In the event two or more hospitals are competing to meet the same forecasted net need, the department shall consider the following factors within determining which proposal best meet forecasted need.
(i) The most appropriate improvement in geographic access;
(ii) The most cost efficient service;
(iii) Minimizing impact on existing programs;
(iv) Providing the greatest breadth and depth of cardiovascular and support services; and
(v) Facilitating emergency access to care.

Consistent with this standard, the department is evaluating this project under concurrent review with the joint project submitted by Evergreen Hospital Medical Center and Overlake Hospital Medical Center. Therefore, this standard applies to this project.

Standard #g:
Hospitals granted a Certificate of Need have three years from the date the program is initiated to establish the program and meet these standards.

As stated in Standard #a, Step #6 of the methodology projects approximately 492 additional OHS will be performed in HSA #1 by year 2006. GSH anticipates providing 264 surgeries by the end of its third year of operation, however, as stated in standard #c in this evaluation, GSH is expected to achieve this volume at the expense of reducing an established program below the 250 volume

standard. Further, OHS volumes are declining in the HSA and Washington State. This decline is not limited to Washington State or HSA #1; data reviewed by the department demonstrates that OHS procedures have been declining nationally. Based on these factors, the department is unable to conclude that GSH's projections are attainable or reasonable. This standard is not met.

Concerns raised in opposition to this project related to the OHS standards under WAC 246-310-261 were provided by MultiCare Health System on behalf of Tacoma General Hospital and Franciscan Health System on behalf of St. Joseph Medical Center. The department has restated or summarized the concerns from both entities below.

Tacoma General (restated)

> GSH application does not meet the open-heart surgery standards set forth in WAC 246-310-261. [source: public comments provided at January 16, 2003, public hearing]

St. Joseph Medical Center (summarized)

- the open heart impact on existing Tacoma providers--especially in light of the program expected to open in Kitsap County at Harrison Memorial Hospital within the next several months; and
- the lack of verifiable cases from Good Samaritan's active medical staff.
  [source: public comments provided at January 16, 2003, public hearing]

Tacoma General Hospital did not provide specific data, documentation, or discussion regarding the methodology and standards. Without specific information, the department is unable to ascertain, evaluate, and address Tacoma General Hospital's concerns.

St. Joseph Medical Center provided detailed information regarding the impact of the proposed program on existing providers in HSA #1 and specifically Tacoma General Hospital. The department addressed the impact of GSH's proposed OHS program in detail under Standard #c of this evaluation.

St. Joseph Medical Center also provided information to demonstrate that GSH referral documentation is not verifiable. In response to this assertion, GSH performed an extensive re-evaluation of its referral documentation and concluded that it had double counted one referral, resulting in 284 referrals rather than 285. Given the extensive re-evaluation performed by GSH, the department concludes that GSH's active medical staff referred 284 cases.

Additionally, the University of Washington Medical Center (UWMC) provided comments regarding this application. After reviewing the comments, the department concludes that UWMC is neither in support or opposition to the GSH project. The comments are restated below, and have been addressed within the standards review portion of this evaluation.

University of Washington Medical Center (restated)

> UWMC requests that in its review of these two applications, the Department of Health recognize the special needs of medical education programs. It is critical that the volumes of cardiac bypass graft cases and valve replacement cases in the training programs in our state remain at levels sufficient to provide high quality education experiences for surgeons in training. [source: public comments provided at January 16, 2003, public hearing]

Information provided by University of Washington Medical Center was considered in the evaluation of this project.

Based on the above evaluation, the application submitted by Good Samaritan Hospital proposing to establish a regional open heart surgery program and PTCA service is not consistent with the standards outlined in WAC 246-310-261.

B. Nonemergent Interventional Cardiology Standard (WAC 246-310-262)

Based on the source information reviewed, the department determines that the applicant has not met the standards in WAC 246-310-262.

All nonemergent percutaneous transluminal coronary angioplasty (PTCA) procedures and all other nonemergent interventional cardiology procedures are tertiary services as defined in WAC 246-310-010 and shall be performed in institutions which have an established on-site open heart surgery program capable of performing emergency open heart surgery.

This criteria states that an applicant must have an on-site OHS program before it provides PTCA services. Given that GSH's application to establish OHS services at the hospital is not consistent with the applicable criteria under WAC 246-310-261, GSH is precluded from providing OHS services, and, as a result, may not establish PTCA services. Therefore, this criterion is not met.

Based on the above evaluation, the application submitted by Good Samaritan Hospital proposing to establish a regional open heart surgery program and PTCA service is not consistent with the criterion in WAC 246-310-262.

C. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that the applicant has not met the need criteria in WAC 246-310-210.

(1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.

WAC 246-310-210 requires the department to evaluate all Certificate of Need applications on the basis of the population's need for the service. Information provided by GSH to support this criterion is summarized below. [source: Application, pp15-17]

> *There are neither cardiac surgery nor elective interventional cardiology services in the Good Samaritan primary and secondary service areas. The vast majority of patients in the primary and secondary service area travel to Tacoma for these services. The current lack of these services in Puyallup negatively impacts the residents of the defined services area in a number of ways. The need for this new service can be evaluated against the criteria of patient access, quality of care, and the long-term viability of GSH.*
>
> *Patient Access*
>
> *For patients in the defined service area, traveling to Tacoma or elsewhere for elective intervention and surgery may not compromise clinical quality in many circumstances. However, in most circumstances, patient, family and referring physician convenience are enhanced by having services available in the community.*
>
> *Quality of Care*
>
> - *Discontinuity of Care-patient treatment must be interrupted for transport, physicians must transfer the care of the patient to other physicians who have likely never seen the*

patient before, primary care physician is unavailable for ongoing patient follow up and the family is disrupted by having to travel to be with their loved one.

- *Bed availability-with limited bed capacity at GSH, the unnecessary days of stay awaiting transport contribute to an ongoing problem*
- *Risk of transport-accidents occur in both ground and air transport situations with injury or death that can be avoided if adequate services were available in the community.*
- *Retention of trained cardiologists- The presence and availability of expanded cardiac services at GSH will better enable the hospital to attract and retain additional highly trained and experienced cardiologist necessary to ensure the level of care in the region continues to meet the national standards of care.*

Long Term Viability of the Hospital

- *Positioning for managed care-the evolution of managed care is forcing providers to examine their continuum of care and enhance program comprehensiveness. Providers that are best able to control both quality and costs are those that provide comprehensive services. The addition of expanded cardiac services at GSH will enable GSH and its physicians to offer a more complete range of services and better control the delivery of those services.*
- *Absence of comprehensive services-the absence of comprehensive cardiac services at GSH could result in a long term loss of market share. Once a patient goes to another facility for their care, because of a lack of comprehensive services at GSH, it is more likely for that patient to look to another provider in the future. Many patients who have been sent elsewhere for comprehensive cardiac care may never return to GSH because of an impression that it is not a full-service hospital.*
- *Strategic vision-as detailed in this application, the addition of cardiac surgery services in integral to GSH achieving its vision as a successful regional medical center.*

For an OHS project, the sub-criterion under need requires the applicant to demonstrate that the population to be served has need for the project and other OHS facilities are not or will not be sufficiently available or accessible to meet the need. GSH does not provide documentation to support that the patients have a need for this project and other facilities are not available to meet that need. In fact, within its CN application, GSH states "…*for patients in the defined service area, traveling to Tacoma or elsewhere for elective intervention and surgery may not compromise clinical quality in many circumstances"* and further states *"while patients residing in the service area appear to receive good care once they reach the hospital in Tacoma, the lack of on site elective interventional cardiology and cardiac surgery services impacts the quality of care in a number of ways…."* GSH then provides statements related to the hospital's need to provide OHS in the community.

As previously stated in the project description portion of this evaluation, open heart surgery and PTCA are tertiary services as defined in WAC 246-310-010, and therefore require sufficient patient volumes to optimize provider effectiveness, quality of service, and improved outcomes of care. For these reasons, open heart surgery is not, and should not be, offered in every hospital within the state. With a tertiary service, it is expected that a patient will be transported some distance to receive quality care from a quality provider. To become a quality OHS and PTCA provider, a hospital must be able to meet the standards set forth in WAC 246-310-261 and -262. GSH was not able to meet those standards without negatively impacting an established OHS provider. Further, information provided by GSH to demonstrate need for the program focused on GSH's need to establish an OHS program for its financial viability, perception in the community, and to attract and retain physicians. While these may be valid reasons to begin some services at a hospital, for Certificate of Need

purposes, this is not considered a valid demonstration of need. Further, the connection among sufficient patient volumes, quality of care, and improved outcomes for tertiary services requires a substantial and compelling demonstration of need for the services by the patient and the community.

Additionally, in order to maintain itself as a quality provider with improved outcomes for OHS services, GSH would have to continue to perform at least 250 OHS per year. Given the decrease of OHS in HSA #1 and Washington State as a whole--a common trend across the nation--the department is not confident that GSH could perform 250 OHS by the end of the third year of operation or maintain the required 250 volume in subsequent years.

Concerns raised in opposition to this project related to the need criteria were provided by MultiCare Health System on behalf of Tacoma General Hospital. The department has restated those concerns.

Tacoma General

> GSH has not shown that the need criteria set forth in WAC 246-310-210 will be satisfied, including, but not limited to, the requirements that (1) the population to be served as a need for the project, and (2) other services or facilities are not sufficiently available or accessible to meet any need that may exist.

Tacoma General Hospital did not provide specific data, documentation, or discussion regarding need. Without specific information, the department is unable to ascertain, evaluate, and address Tacoma General Hospital's concerns.

In summary, the department concludes that GSH did not demonstrate that the population served or to be served has need for the OHS and PTCA services and existing facilities are not or will not be sufficiently available or accessible to meet that need as required in WAC 246-310-210. This sub criterion is not met.

(2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

All residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups currently have access to services at GSH. The approval of OHS and PTCA services at the hospital is not expected to change this access. Additionally, admission policies provided by the applicant demonstrate that patients are admitted to the facility for treatment without regard to age, race, color, religion, sex, national origin, handicap, or sexual preference and will be treated with respect and dignity. [source: Application, Appendices 7 and 8]

For charity care reporting purposes, OHPDS, divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. GSH is one of 18 hospitals located within the Puget Sound Region. According to 1999–2001[7] charity care data obtained from OHPDS, GSH has historically provided an average of charity care greater than the Puget Sound regional average. GSH's most recent three years (1999-2001) percentages of charity care for gross and adjusted revenues are 1.77% and 3.25%, respectively. The 1999-2001 average for the Puget Sound Region is .94% for gross revenue and 1.81% for adjusted revenue. [source: OHPDS 1999-2001 charity care summaries] GSH's pro formas and current charity care policies both indicate that the hospital will provide charity care, although the percentage of charity care to be provided is not identified in either document. [source: Application, Appendix 8 and GSH October 31, 2002, supplemental responses, revised Appendix 14] Therefore, the department concludes that all residents of

[7] Year 2002 charity care data is not available as of the writing of this evaluation.

the service area would have adequate access to the health services at GSH. This sub-criterion is met.

D. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed, the department determines that the applicant has not met the financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met.

To analyze short- and long-term financial feasibility of hospital projects and to assess the financial impact of a project on overall facility operations, the department uses financial ratio analysis. The analysis assesses the financial position of an applicant, both historically and prospectively. The financial ratios typically utilized are **1)** long-term debt to equity ratio; **2)** current assets to current liabilities ratio; **3)** assets financed by liabilities ratio; **4)** total operating expense to total operating revenue ratio; and **5)** debt service coverage ratio. If a project's ratios are within the expected value range, the project can be expected to be financially feasible.

For the GSH project, the only ratios that apply are the long-term debt to equity ratio and the total operating expense to total operating revenue ratio. The remaining ratios are more appropriate to evaluate when an applicant intends to finance a project from an outside source. For this project, GSH intends to fund the $1,646,440 capital expenditure with board designated assets. [source: Application, p9, and OHPDS analysis, p2] Table IX below shows the two applicable ratios for this project, in the first three years of operation for the hospital as a whole, with the OHS and PTCA services, and the Office of Hospital and Patient Data Systems (OHPDS) year 2001 financial ratio guidelines for hospital operations. [source: OHPDS analysis, pp2-3]

Table IX
Good Samaritan Hospital's Current and Projected Financial Ratios

Financial Ratio	OHPDS Guideline		GSH Current Year 2001	Year 1 2003	Year 2 2004	Year 3 2005
Long Term Debt to Equity	0.529	* Below	.429	n/a	n/a	n/a
Total Operating Expense to Total Operating Revenue	0.976	* Below	.966	1.191	1.080	1.016

* = a project is considered more feasible if the ratios are above or below the value/guideline as indicated

After reviewing the financial information provided by GSH, staff from OHPDS stated the following:

> *"[the] Long-Term Debt to Equity ratio at the end of 2001 is .429, which is below the 2001 state average of .529 as calculated by [this office]. Good Samaritan Hospital has taken on debt recently; its Long-Term Debt to Equity Ratio at the end of 2000 was only .019. The hospital has performed adequately in the past and this ratio is appropriate.* [source: OHPDS analysis, p2]

Additionally, as previously stated in this evaluation, GSH projects 168 OHS in year one (2004), 223 in year two, and 264 by the end of the third year of operation (2006). Based on those projections, Table X shows the revenue, expenses, and net income projected by GSH for the first three years of operation for its OHS and PTCA program. [source: Application, p8 and GSH December 2, 2002, supplemental information, Revised Appendix 14]

Table X
Good Samaritan Hospital's
Projected Revenue and Expenses for OHS and PTCA Program

	Year 1 -- 2004	Year 2 -- 2005	Year 3 -- 2006
Projected # of OHS patients	168	223	264
Projected # of PTCA patients	210	280	330
Projected # of patient days (OHS & PTCA combined)	1,810	2,462	3,122
Net Patient Revenue	$ 7,401,351	$ 10,276,533	$ 13,210,675
Operating Expense	$ 8,815,918	$ 11,103,385	$ 13,424,235
Annual Net Income/(Loss)	($ 1,414,567)	($ 826,852)	($ 213,560)

Operating Revenue per Pt. Day	$ 4,089	$ 4,174	$ 4,231
Operating Expense per Pt Day	$ 4,871	$ 4,510	$ 4,300
Net Income/(Loss) per Pt. Day	($ 782)	($ 336)	($ 68)

As noted in Table X above, GSH projects a net loss for its OHS and PTCA program in all three years of operation. The pro forma expenses shown above include allocated costs. These costs represent the OHS and PTCA program's fair share of hospital non-revenue producing expenses (such as administration). With these costs included, operating revenues are not expected to exceed operating expenses by the end of the third year of operation.

After reviewing the financial information provided by GSH, staff from OHPDS stated the following:

> *"The hospital does not show the new Open Heart Surgery program revenue covering the direct expenses and the fully allocated expense. However Good Samaritan indicates that the project will break even in the 11th month of the third year. The projected income statement supports the claim that Good Samaritan will break even within the third year. Good Samaritan Hospital's financial health is above average as compared to other community hospitals whose data is collected by this office."*

GSH anticipates that the OHS and PTCA program will break even and then begin to cover costs in its fourth year of operation, and based on the volume projections by GSH, OHPDS concludes these revenues can be achieved.

In the need section of this evaluation, the department voiced concerns regarding GSH's ability to achieve its projected volumes and maintain those volumes given the decline in OHS procedures within the HSA, Washington State, and across the nation. However, based solely mathematical calculations within the methodology and referral documentation provided by GSH, the department concludes that GSH's projections are reasonable and the hospital would be able to meet its short and long term financial obligations, and its capital and operating costs of the project would be met. This sub-criterion is met.

(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

OHPDS also compared GSH's costs and charges to the year 2001 statewide average and determined that they are reasonable. [source: OHPDS analysis, p3]

As previously stated, the capital expenditure for the OHS and PTCA program at GSH is projected to be $1,646,440, and the majority of the expenses (69%) is related to purchasing equipment for the new program. [source: Application, p28]

In the need section of this evaluation, the department concluded that GSH failed to demonstrate that the population has a need for this project and existing providers are not available to meet the future need for OHS and PTCA services in the community. Given that the project is not necessary, the department also concludes that the costs of this project will probably result in an unreasonable impact on the costs and charges for health services in the community. This sub-criterion is not met.

(3) The project can be appropriately financed.

The $1,646,440 capital expenditure for this project will be funded from board designated assets (or hospital reserves) from funds generated from operations. [source: Application, pp8-9]

After reviewing GSH's September 30, 2002, audited financial report, staff from OHPDS provided the following evaluation:

> *"Good Samaritan Hospital indicates it will use reserves (board designated assets) to finance this project. $1,646,440 is .81% of total assets and approximately 2.78% of reserves when compared to the 2002 fiscal year end balance sheet. The use of reserves is very inexpensive. Reserves are accumulated mainly from prior year profits. The only cost would be that the money would not be available for other uses. This project will not impact reserves, total assets, total liability, or the general health of the hospital in a significant way."* [source: OHPDS analysis, p2]

As noted by OHPDS, the capital costs for this project will not have an effect on the hospital's reserves, nor will it adversely affect the hospital's total assets, total liability, or general financial health. Therefore, the department concludes that the proposed financing is appropriate, and this sub-criterion is met.

Concerns raised in opposition to this project related to the financial feasibility criteria were provided by Franciscan Health System on behalf of St. Joseph Hospital. The department has restated those concerns.

St. Joseph Hospital

> *"…The Good Samaritan project also fails to demonstrate financial feasibility. The CN Program has a long history of mandating that new hospital projects include fully allocated costs and that they break even by the end of the third full year of operation. Good Samaritan itself notes that its revenue--the revenue projected to be generated by the service--does not cover the expenses associated with the project within the first three years."*

The department previously addressed St. Joseph Hospital's concerns and concluded that, based solely on mathematical calculations within the methodology and referral documentation GSH would be able to meet its short and long term financial obligations, and its capital and operating costs of the project would be met.

E. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed, the department determines that the applicant has not met the structure and process (quality) of care criteria in WAC 246-310-230.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

As stated in the project description portion of this evaluation, to assist in its staff recruitment and assure that the staffing levels are appropriate for the proposed program, GSH has entered into a draft agreement with Starr-Wood. The draft agreement outlines the roles and responsibilities of each

entity and identifies all costs associated with the agreement. Under this agreement, Starr-Wood will be responsible for start up and ongoing operations of the program, initial training of the staff, and providing the medical director and cardiologists. GSH will have final authority for management and operations, recruitment of staff, and provide equipment and supplies for the proposed program. [source: GSH December 17, 2002, supplemental information]

In response to this criterion, GSH states the following:

> *"Good Samaritan Hospital is certainly not immune to the nationwide shortage of nursing and other technical staff. Staff recruitment and retention activities to ensure that the staffing needs of the hospital continue to be met. GSH continually reviews its salary and benefits levels to ensure that it competes well with other hospitals in the region. It is anticipated that a number of current GSH staff will be interested in filling a certain [number] of the new positions. The startup of a new cardiac surgery and elective interventional program is anticipated to be a significant recruitment incentive to those persons looking for a clinically challenging career opportunity."* [Source: Application, p34]

As of the writing of this evaluation, GSH currently operates a diagnostic and emergent interventional cath laboratory. GSH states that the lab is fully staffed by qualified and experienced personnel who will form the core group of the staffing for the elective interventional program. GSH does not anticipate any difficulties in recruiting and staffing the proposed program. [source: Application, p34]

Based on the information provided by GSH in its application and supplemental documentation, the department concludes that GSH's proposed OHS and PTCA program would be sufficiently staffed and this sub-criterion is met.

(2) *<u>The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.</u>*

GSH states it will continue to use its existing protocol for transporting complex OHS patients to the hospitals and physicians in Tacoma. As stated in the project description portion of this evaluation, GSH will serve patients 15 years of age and older. Patients 14 years and younger will primarily be referred to Mary Bridge Children's Hospital in Tacoma or Children's Hospital and Regional Medical Center in Seattle. GSH anticipates no change in the pediatric referral patterns with the establishment of the proposed adult OHS and PTCA services. [source: October 31, 2002, supplemental responses, p3] The department concludes that this sub-criterion is met.

(3) *<u>There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.</u>*

GSH will continue to provide Medicare and Medicaid acute care services to the residents of the service area. Within the most recent four years, the Department of Health's Office of Health Care Survey (OHCS), which surveys hospitals within Washington State, has completed one compliance survey for the hospital.[8] The survey revealed minor non-compliance issues typical of a hospital, and GSH submitted a plan of corrections for the non-compliance issues within the allowable response time. [source: compliance survey data provided by Office of Health Care Survey]

GSH identified the Starr-Wood physician members to be associated with its OHS and PTCA program and named Albert Starr, MD as the proposed medical director for the program. A review of the physician members' and medical director's compliance history with the Department of Health's

[8] Survey conducted 2000.

Medical Quality Assurance Commission reveals no recorded sanctions for all. [source: compliance history provided by Medical Quality Assurance Commission] Given the compliance history of GSH and the proposed physicians, there is reasonable assurance that the proposed OHS and PTCA services would be operated in conformance with applicable state and federal licensing and certification requirements. This sub-criterion is met.

(4) *The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.*

In response to this criterion, GSH states the following:

> *"Continuity in the provision of state-of-the-art cardiac care is a key factor for the proposed program, and quality of care is negatively impacted by the discontinuity of care in the current situation. Patient treatment must be interrupted for the transport, physicians must transfer the care of the patient to other physicians who have likely never seen the patient before, the primary care physician is unavailable for ongoing patient follow up and the family is disrupted by having to travel to be with their loved one. Each of these factors can ultimately contribute to lesser outcomes in the treatment of the patient and cause disruption to the family lives of the residents of Puyallup and surrounding areas. Additionally, continuity in care is enhanced by an adequate number of skilled physicians serving the community. …the availability of expanded cardiac services at GSH will better enable the hospital to attract and retain additional highly trained and experienced cardiologists necessary to ensure that the level of care in the region continues to meet national standards of care. Highly skilled cardiologists coming out of state-of-the-art training programs look for opportunities where they can utilize their skills at the hospital in which they base their practice. The time and effort required by having to travel to Tacoma to perform angioplasty make it more difficult for invasive cardiologists and interventionalists to consider GSH as a location for their practice."*
> [source: Application, pp35-36]

The department understands GSH's argument regarding the transport of patients and disruptions to the family and patient. However, with a tertiary program where there is a direct connection among sufficient patient volumes and provider effectiveness, quality of service, and improved outcomes of care, the department concludes that the establishment of a quality provider in this health care service is far more critical than patient, family, or physician convenience.

The department does not concur with GSH regarding continuity of care. Continuity of care is not limited by a facility. Depending on the patient's needs, continuity of care may include transport of the patient to the most appropriate provider. For tertiary services, continuity of care means a hospital's ability and willingness to triage and transport as necessary to the most appropriate tertiary provider. For emergent OHS or PTCA patients, this will mean that the patient will be transported to a physician or physician group who has not previously seen the patient. In this case, continuity of care also means that the referring hospital provides specific patient information and documentation to the receiving facility. Further, in many instances, a patient's primary care physician is not a cardiologist, therefore, for cardiac services, the patient would expect to see a new, different physician. GSH further indicates that if an OHS or PTCA patient is transferred to another facility, *the primary care physician is unavailable for ongoing patient follow up*. The department is unsure what GSH means by this statement. Again, continuity of care also includes the communication and sharing of patient information between physicians in different facilities or physicians within the same facility.

Additionally, the department concluded that that OHS volumes are declining in HSA #1 and Washington State, and, therefore, was not confident that GSH could reach 250 OHS by the end of the third year of operation or maintain the required 250 volume in the subsequent years. The

department also concluded that the establishment of GSH's OHS and PTCA program could reduce an existing, established provider below the 250 standard. If both of the department's concerns were realized, the result would be two OHS and PTCA programs operating below the 250 standard and potentially unable to maintain quality programs. The final result would be a fragmentation of existing services. Therefore, the department concludes that approval of this project has the potential of fragmentation of OHS and PTCA services within HSA #1. Therefore, this sub-criterion is not met.

(5) *There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.*
This sub-criterion is addressed in sub-section (3) above.

F. Cost Containment (WAC 246-310-240)
Based on the source information reviewed, the department determines that the applicant has not met the cost containment criteria in WAC 246-310-240.

(1) *Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.*
Before submitting this application, GSH considered and rejected the option below.

Status Quo
This option was dismissed by GSH as nonviable because of the previously stated continuity of care and cost of care issues. GSH asserts that the most clinically appropriate and cost-effective way to provide state-of-the-art cardiac surgery services to residents of the GSH service area is to establish the OHS and PTCA services at GSH campus. GSH further states that numerous factors, including continuity of care, cost of care, and quality of care make the proposed program the best alternative for serving the healthcare needs of the residents in and around Puyallup. GSH asserts that the proposed program will promote efficiency in the delivery of cardiac surgery and elected PTCA procedures and enhance the provision of cardiac care to the residents of the service area, eliminate duplication, and reduce overall costs in the delivery of health care. [source: Application, p38]

Under the need portion of this evaluation, the department concluded that GSH failed to demonstrate that the proposed project is needed within the community. Given that the project is not needed in the community, the department also concluded within the financial feasibility portion of this evaluation that the proposed program will result in an unreasonable impact of costs and charges for health services. Additionally, under the structure and process of care criterion, the department expressed concern about the proposed project contributing to an unwarranted fragmentation of OHS and PTCA services.

Additionally, for reasons stated within this evaluation, the department concluded that GSH's proposed project does not conform to the OHS and PTCA standards (WAC 246-310-261 and -262, respectively), or meet the criterion of need (WAC 246-310-210), financial feasibility (WAC 246-310-220), and structure and process of care (WAC 246-310-230). Therefore, the department does not conclude that approval of this project is the best available alternative for the residents of GSH service area.

On the basis of these conclusions, the department concludes that approval of this project is not the best available alternate for the service area, and this sub-criterion is not met.